February 1, 2016

The Honorable Andy Slavitt,
Acting Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3323-NC
Submitted electronically at: http://www.regulations.gov

Re: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs

Dear Administrator Slavitt:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding this Request for Information (RFI) on Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs. This RFI was published by the Centers for Medicare & Medicaid Services (CMS) in the December 31, 2015, issue of the *Federal Register*.

AMIA is the professional home for more than 5,000 informatics professionals, representing researchers, front-line clinicians and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA members play a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

Although we appreciate that CMS is seeking critical feedback on the certification aspect of its quality measure reporting strategy in anticipation of MACRA-related policies, we want to emphasize that the questions posed in this RFI, with their focus on enhanced certification as a potential remedy, do not address the fundamental deficiencies and challenges with the process of generating electronic clinical quality measures (eCQMs) as well as reporting the measures.

This focus on certification is therefore problematic because it suggests a view that certification enhancements are a promising way to address the problems with quality measurement that have emerged, and we do not believe this is the case. Providers have very little, if any, confidence in eCQM accuracy and completeness; health IT developers spend an inordinate amount of resources devoted to eCQMs, which represents an opportunity cost for other customer priorities; and there is little time for the stakeholders to incorporate updates into their products and workflows. In short, the task of gathering and reporting eCQMs overshadows the benefits of tracking measures in many instances.

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We anticipate that, as CMS develops new requirements for the Merit-based Incentive Program System (MIPS) and Alternative Payment Models (APMs), healthcare will see a proliferation in the volume and diversity of quality measures needed for reimbursement. Unfortunately, the paradigm currently in place to create and certify eCQMs simply will not scale to this fast-approaching future.

Consistent with recommendations included with the *Report of the AMIA EHR 2020 Task Force on the Status and Future Direction of EHRs*,[1] we call on CMS to overhaul how quality measures are developed and conceptualized in an electronic environment. Federal officials have a rare opportunity to reimagine CQMs given the continued proliferation of electronic health records (EHRs) and new policymaking authority under MACRA. This overhaul must begin with a better process, which should include pilot testing and an assessment of how implementable the new measure is for the target population of providers. It is not enough that a measure be deemed clinically appropriate for endorsement; the measure should also be demonstrably implementable in the clinical setting, in a way that enhances patient experience.

Further, we encourage CMS to take advantage of the options we now have with discrete digital data to better define quality on a longitudinal scale. The value of measuring quality, especially outcome-based measures, is in enabling longitudinal views of a patient and patient populations. This longitudinal approach ensures that clinical trending and trajectory is consistently understood by both providers caring for patients, the patients and their families, and organizations paying for such care. It is AMIA's strong belief that the quality of care models introduced through MACRA will be best measured as trajectory rather than thresholds.

As additional components of this overhaul, AMIA recommends CMS:

- Find consensus on how to construct measures based on the capabilities of EHRs in use and other health IT used for data collection and reporting, not solely on what the ideal measure of quality might be;
- Develop and implement methods to estimate and consider the cost – in time and effort – of data collection as well as the likely benefits to patients of a new measure, so we understand the benefits and opportunity costs of collecting additional data for quality purposes;
- Consider a separate endorsement path for electronically specified measures that considers feasibility of workflow implementation, and includes pilot testing, for the practice setting for which the measure is intended;
- Build stability and consistency year-over-year in what is measured and reported, across programs and in coordination with other payers, so that longitudinal measurement is possible;

[1] Payne T., Corely S., et al. Journal of the American Medical Informatics Association. Sep 2015, 22 (5) 1102-1110; DOI: 10.1093/jamia/ocv066

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- Invest in the infrastructure for robust and effective testing by improving the quality of test data and testing tools; and
- Enable novel groupings of healthcare teams and/or multiple clinicians who coordinate care on a patient to report CQMs as a group.

The path to this overhaul is best built in close coordination with specialty societies, and with much more interaction between measure developers and the clinicians who use those measures. CMS has indicated in recent policies it is considering ways to impart key responsibilities to specialty societies in helping to develop MACRA-related policies, including in determining what evidence-based quality measures are important to track for their patient populations. **AMIA supports the direction of this kind of policymaking, as specialty societies are well positioned to help define quality measures, clinical practice improvement efforts and can be important resources for federal regulators.** More work is needed however, to assure that specialty societies use a consistent set of data standards and formats in their quality measures. This will simplify how EHRs collect quality measurement data for different specialty society measures. As it relates to quality reporting, this approach will depend on a strong centrally-defined set of standard technical building blocks and a well-defined pattern of development, testing, implementation and feedback within a reasonable timeline.

Questions posed by this RFI represent important programmatic decisions, so it is with the preceding recommendations in mind, we offer comment within the context of the current environment. Specific to the questions in this RFI, AMIA recommends:

- CMS not change its policy to one of requiring recertification for annual updates to existing deployed CQMs, but rather focus on improved testing through enhanced testing tools and test data for updates;
- For new measures, CMS work more closely with ONC so that certification yields better assurance to providers that CQM data gathered and calculated will be successfully accepted by CMS.
- CMS develop a regular cycle of updates on a consistent basis, both as a consequence of changes in evidence and changes to CQM specifications;
    - Such updates should include a discretionary period of use by providers for a period of one year before the updates are mandatory; and
    - Such updates should not require certification unless they are new measures, in which case there should be a period of pilot testing before it is required for reporting;
- CMS rely on specialty societies to guide prioritization of quality measure sets for MACRA-related programs;
- CMS construct a "core" requirement for which vendors must certify based on setting, e.g. ambulatory and inpatient, while also requiring developers certify to those measures

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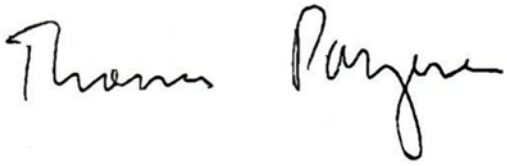
they intend to offer based on the expressed needs of their client base, guided by suggested measure sets identified by specialty societies.

Although not explicitly stated in this RFI, CMS has indicated previously an interest in requiring CQM submissions by providers on a more frequent basis, such as quarterly submission. Successful implementation and deployment of new and revised eCQMs is predicated on a series of timely actions following finalization of a rule in the *Federal Register*. Some of these steps are well articulated in the CMS Measure Management System Blueprint.[2] We urge CMS and ONC to consider this Blueprint when developing a regular pattern of updates, or when considering submission of eCQMs on a more frequent basis, as more frequent updates will likely cause a more heterogeneous mix of eCQM versions.

We hope our comments, attached below in Table 1, are helpful as you undertake this important work. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA



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[2] Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html

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Table 1

RFI Questions	AMIA Response
FREQUENCY OF CERTIFICATION	
In General: CMS understands that health IT developers must make CQM updates annually and providers must regularly implement those updates to stay current with the most recent CQM version. CMS also understands that standards for electronically representing CQMs continue to evolve, and they believe there may be value in retesting certified Health IT Modules (including CEHRT) periodically to ensure that CQMs are being accurately represented, and that they can be reported as required. While CMS believes health IT developers should test and certify their products to the most recent version of the electronic specifications for the CQMs when feasible, they understand the burdens associated with this requirement and therefore, have not historically required recertification of previously certified products when updates are made to CQM electronic specifications or to the standards required for reporting. CMS seeks input on changes to this policy. **AMIA Comment:** We believe CMS should develop a regular cycle of updates on a consistent basis, both as a consequence to changes in evidence and changes to CQM specification. It is vital that this cycle take into account the process of finalizing measure specifications, not just finalization of the measure. A sensible cadence of updates would have finalized CQM specifications published in the fall for EPs, followed by a discretionary period of use by providers beginning the following January 1 for a period of one year, before those measures are made mandatory. In general, we do not believe that CMS should change its policy to one of requiring recertification for annual updates to existing deployed CQMs.	

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Frequency of Certification	**Q1:** CMS asks for comment on the requirement for CEHRT products to be recertified when a new version of the CEHRT is available in order to ensure the accuracy of implementation.	We support what we understand to be the current requirement for CEHRT products to be recertified when a new version of the CEHRT is available that affects quality measure reporting functionality. The question then becomes how quickly after new CEHRT is finalized will vendors / providers be required to implement? Given experience to-date, we believe a reasonable policy would require implementation of new CEHRT not less than 24 months following finalization of specifications for the new CEHRT. Successful implementation of new CEHRT or newly certified functionality is predicated on a series of timely actions following finalization of a rule in the *Federal Register*. Any program that relies on certified technology for participation must take this lifecycle into account.
	Q2: CMS asks for comment on the requirement for Health IT Modules to undergo annual CQM testing through CMS approved testing tools and the ONC Health IT Certification Program.	We believe CMS should update measures only when evidence indicates a change to an existing CQM is essential, or when a technical error in specification is identified. When such updates are necessary, we support publication of those changes as part of a well-defined annual process. However, we recommend that new or modified measures not be required for use during the first calendar year after publication of final specifications. In such circumstances, we recommend that providers be required to use the most recent version of the electronic specification for e-reporting, but not be required to use recertified (for the measure update) EHR technology. Rather, we suggest vendors be required to attest that in the process of updating measures they have applied due diligence in testing

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		with the Cypress tool, or some other CMS-designated testing tool during the period after finalization of CQM specifications.
	Q3: What is the burden (both time and money) of additional testing and recertification?	Estimates vary, but one member reports roughly 20 person hours per measure to prep for certifying. Another member indicated that recertification for multiple measures was between 10 and 20 person weeks of effort. The challenge is that quality measure updates come as a bolus, so resources are diverted from development and testing processes to accommodate the certification activities. The opportunity costs—specifically the loss of opportunity to enhance EHR products in other important ways to improve the patient experience—must be considered. Because certification requires engagement with an outside party and involves significantly more time and expense, we do not believe it is reasonable to expect that the nation's EHR vendors could accomplish the certification process in the 60-day window between finalization of updates, and the beginning of a new reporting year. If our earlier recommendation is applied, CMS should make reporting of changed or updated CQMs provision for the next year following finalization of measure specification, and we would encourage pilot testing to occur during this time.
	Q4: What are the benefits of requiring additional testing and recertification?	We believe the benefits of additional testing outweigh those of recertification, and would encourage CMS to focus on the former.
	Q5: How will it [annual recertification] affect the timeline for CQM and standard updates?	Should standardized and documented testing, rather than certification/recertification, be used, annual CQM and standards updates should be feasible, but annual updates should still only reflect essential changes and HIT developers and providers will need more than 60 days to develop and implement CQMs many cases.

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	Q6: What are the benefits and challenges of establishing a predictable cycle from measure development to provider data submission?	Benefits of a predictable cycle are very high. However, we are concerned the timeline from development to provider data submission is too condensed. And we note that more frequent / earlier submission deadlines amplifies the timing challenges.
CHANGES TO MINIMUM CQM CERTIFICATION REQUIREMENTS		
In General: As part of the 2014 Edition Base EHR, certified products must be certified to a minimum of 9 CQMs (EPs) or 16 CQMs (EHs). CMS believes EHRs should be certified to more than the minimum number of CQMs because this minimum number may limit EPs, EHs and CAHs from being "able to report on CQMs that are applicable to their patient population or scope of practice." Accordingly, they are soliciting comment on the following policy options that could provide greater choice for EPs, eligible hospitals, and CAHs. Specifically, they are interested in (1) the feasibility of health IT developers complying with the requirements of each option in the first year in which the requirements would become effective; (2) the impact of each option on EPs, EHs/CAHs and health IT developers; and (3) what CMS would need to consider when assessing each of these options. **AMIA Comment:** Our primary recommendation is to require an approach where vendors support CQMs spanning a "core" set of measures, depending on ambulatory or hospital setting, as well as CQMs developed for specific client types, depending on a vendor's customer base. We further recommend CMS work directly with specialty societies to determine which measures could be grouped or clustered, using the current PQRS reporting options as potential models. We believe this approach strikes a balance resulting in flexibility for vendors to seek certification for the kinds of measures most relevant to their customer base, and optionality for clinicians to prioritize measures according to their practice and patient populations. This also provides a basic comparability among provider types, e.g. cardiologists, and settings, e.g. hospitals. To operationalize this recommendation, we encourage CMS explore the use of Measures Group Reporting and Measure-Applicability Validation process clusters. These groups and clusters could be developed in concert with national associations for primary and specialty providers to ensure relevance. Vendors could then select the bundles that best represent their customers, and there would be overlap among some of the bundles, so vendors would not necessarily have to support all CQMs. We further propose that CQM bundles be coordinated in direct discussion with relevant provider associations after the RFI has closed, and not based solely on responses to this RFI.		

RFI Questions		AMIA Response
Changes to Minimum CQM Certification Requirements	**Q7: Option 1:** Require EP health IT developers to certify Health IT Modules to all CQMs in the EP selection list; and require eligible hospital/CAH health IT developers to certify to all CQMs in the selection list for eligible hospitals and CAHs. 64 EPs; 29 EH full list	Feasibility: Given our view that MIPS and APMs will generate a substantial increase in the number and types of quality measures, we do not believe Option 1 is practical, especially for EPs. Our vendor contributors note the substantial overhead from coding to managing the lifecycle of any given measure, and they note this is an opportunity cost that diverts resources from other development priorities including those requested by clinician users. For hospitals, Option 1 may be more feasible, given that most inpatient EHRs are certified to the entire list of 29 measures. However, we remain convinced this is a less desirable approach.
		Impact (EPs; EHs/CAHs; Developers): It is our view that requiring certification to all CQMs is an attractive concept for clinicians, on its face, but the least practical approach for our shared circumstance, including diversion of vendor resources from other clinician development priorities. The initial impact of Option 1 on clinicians would be favorable with more options from which to choose. However, the requirement for every vendor to certify to all CQMs would require extensive additional development time and divert resources and could increase overall EHR complexity with designs to support so many measures.
		Considerations for CMS: We encourage CMS to determine how vendors have sought to satisfy clinicians' quality measure needs, and better understand how a mandate to require might improve (or not) progression to-date. We suspect there is a need to have minimum requirements in some cases, and a need to enable/encourage broader coverage of CQMs in other cases.

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	Q8: Option 2: Incrementally increase the number of CQMs required to be certified each year until Health IT Modules are certified for all CQMs available for reporting by EPs, eligible hospitals, and CAHs to meet their CQM reporting requirements. For Option 2, we invite input on the advantages and disadvantages of an incremental increase in the number of CQMs required to be certified each year.	Feasibility: Similar to Option 1, we do not see this approach as desirable given our shared circumstance. Regardless of whether a product must support all CQMs in year 1 or in year 5, we suspect that ongoing maintenance and support for all CQMs will be unnecessary for vendor types with a narrow customer base and the goal to cover all measures suffers from the same challenges identified for Option 1.
		Impact (EPs; EHs/CAHs; Developers): See "Impact" under Option 1
		Considerations for CMS: See "Considerations" under Option 1
	Q9: Option 3: Require EP health IT developers to certify health IT products to more than the current minimum number of CQMs required for reporting, but not to all available CQMs. For Option 3, we invite stakeholders' input regarding the following approaches that are specific examples of implementation of the policy goal:	Feasibility: As stated in our general comments, a hybrid of Option 3 is our preferred approach. We believe a minimum requirement to cover core measures to hospitals and ambulatory settings, in conjunction with the creation of clinician-specific measure groups/clusters/bundles that are available for use by vendors, based on client preferences, is the right strategy. Such an approach will require close coordination with national associations and professional societies, and it will likely need to evolve over time, somewhat incrementally.
		Impact (EPs; EHs/CAHs; Developers): We believe this approach should give clinicians the flexibility to choose among numerous relevant measures, while not requiring every vendor certify to all CQMs. Vendors that support multiple specialties and settings may support all CQMs in this circumstance, but the "best fit" approach is preferred to the "support all" mandate.

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		Considerations for CMS: We, again, reiterate the need to work closely with specialty care professional organizations to prioritize CQMs, and arrange CQM groupings of relevance.
	Option A: An approach that would set a minimum number of measures health IT developers must certify to for EP settings or eligible hospital/CAH settings that is greater than the minimum number required for provider reporting. For example, EP health IT developers could be required to certify to a minimum of 15 measures, and eligible hospital/CAH health IT developers could be required to certify to a minimum number of 25 measures. Under this approach, health IT developers could choose from any measures in the list of available CQMs.	We believe Option A is part of the hybrid approach CMS should establish. Setting-specific measures are important, but they should not dictate all measure options. We will refrain from specifying an appropriate number of CQMs health IT developers should be require to certify, but experience to-date indicates the proportion of comparable and relevant CQMs may be more numerous for EHs/CAHs than EPs.
	Option B: An EP-specific approach that would require an EP health IT developer to certify to all the measures in a core/required set and all the measures in at least one specialty measure set relevant to the scope of practice for which the product is intended. We are looking for feedback on the general concept of requiring health IT developers to ensure that they are certified to the types of measures that are most relevant to their client base. CMS solicits comment on whether we should require health IT developers to certify to all the measures in a core set depending on whether the	Elements of Option B are another part of our preferred approach, and we support the notion of providing specialty measure sets similar to those recommended under the PQRS which are developed in conjunction with CMS and specialty societies. We do not believe it necessary to develop a category of measures specific to pediatric or adult settings, if our base recommendation is adopted. We also do not agree that vendors should be required to either certify to at least one specialty measure set, or for the measures most relevant to their client base. Simply picking one specialty measure set would be somewhat arbitrary and requiring certification for all measures relevant to a customer base would be highly subjective. Again, beyond the core, we believe that developers should certify to those measures most relevant to their client

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	product is intended to serve pediatric or adult settings.	base, given client priorities, guided by suggested specialty measure sets identified by specialty societies.
	Option C: Another approach with 3 options from which a health IT developer must choose one: 1. Multispecialty health IT developer -– certifies all CQMs. 2. Primary care health IT developer – certifies a set of primary care CQMs. 3. Specialty provider health IT developer – certifies a minimum number of CQMs on an "a la carte" basis. CMS invites general comment on this overall approach.	We reiterate our support for a hybrid approach that includes core measures based on setting of care and supplemented by primary/specialty-relevant measures that are informed by primary and specialty society-suggested measure sets. Option C appears to take a similar approach; however, we believe the categories (multispecialty, primary and specialty) may be overly generic. Option C.1 would likely apply to most EHRs, and would suffer from the defects of Option 1.
CQM TESTING AND CERTIFICATION		
In General: One objective of testing for the 2015 Edition CQM criteria is to increase testing robustness (for example, increasing number of test records, robustly testing pathways by which a patient can enter the numerator or denominator of a measure), thereby ensuring that all certified products have capabilities commensurate to the increased requirements enumerated in the 2015 Edition final rule. CMS expects that "as time progresses and technology improves, EHR systems will have to demonstrate they are able to perform to increasing levels of complexity, including requirements to identify errors, consumer larger numbers of test cases, and demonstrate stricter adherence to standards." CMS and ONC's Health IT Certification Program test CQM functionality (for example, by testing a health IT system's ability to import, export, capture, calculate, and report CQM data according to certain standards) through the Cypress Testing and Certification Tool by enabling repeatable and rigorous testing of a product's capability to accurately calculate CQMs. There are potential areas of improvement to increase the robustness of that testing.		

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AMIA Comment: In our view, there are two types of testing that must occur to better ensure accurate, complete quality measurement: (1) testing for individual, specific quality measures and (2) testing for valid submission of quality measures, generically, based on CMS requirements. We note significant misalignment between what ONC's certification program requires and what CMS requires in order to successfully submit quality data. ONC's certification program contains certain requirements for quality measures, such as the ability to record, calculate, report, import, and export clinical quality measure (CQM) data. But these requirements are not sufficient to meet CMS requirements, which are more complicated, specific and dynamic. At a minimum, this gap must be closed. We recommend that CMS work with ONC so that certification yields better assurance to providers that CQM data gathered and calculated will be successfully accepted by CMS. Further, if CMS were to put more emphasis on testing and piloting eCQMs before their release for use, we anticipate fewer updates / revisions would be needed. Pilot testing would also enable stakeholders to test and validate eCQMs with a higher degree of confidence because the eCQMs have been well-vetted.		
CQM Testing and Certification	**Q10:** What, if any, adverse implications could the increased certification standards have on providers?	As stated before, more robust requirements operationalized through certification does little to ensure better ease of use for providers and the patients they serve. Increased certification standards will require a diversion of resources for developers, which would likely take resources away from addressing needed or desired functionality initiated by customers. An increase in the time vendors must spend certifying new measures may introduce delays adversely affecting release and complexity of updates to providers. Clinicians, too, must update EHR software, build new workflows, test, train, and maintain new functionality.
	Q11: What levels of testing will ensure that providers and other product purchasers will have enough information on the usability and effectiveness of the tool without unduly burdening health IT developers?	In our view, accurate measure calculation that can be accepted by the receiver (CMS) is the most important outcome of testing. The path towards consistently accurate measure calculation is through better test data and varied kinds of testing. We urge CMS to develop better quality test data that represents different patient populations, and represents variation in clinical workflows. Test data should reflect how providers

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		encounter patients and record data; and test data representing a broader variety of patients and scenarios would improve the likelihood of proper implementation of CQMs.
	Q12: Would flexibility on the vocabulary codes allowed for files reduce burden on health IT developers?	We support flexibility in vocabulary code sets, so long as new ambiguities are not introduced. In some cases, such as RxNorm, there is misalignment between when vocabulary codes are updated and when the measures reliant on those codes are finalized. Providers report frustrations when they would like to use a new drug, for example, yet the measure calculation does not allow for the use of the new drug to count towards achievement of the measure. We believe more flexibility would address this issue.
	Q13: When [certification?] requires users to export quality measure data on demand, how would you want that to be accessed by users and what characteristics are minimally required to make this feature useful to end users?	Developers report that "on demand" support is difficult given the size of QRDA files and modern reporting architectures. Given this is a new requirement that is not yet out in most production environments, we encourage CMS to revisit this question to better understand what's required for on-demand functionality.
	Q14: ONC finalized a 2015 Edition certification criterion for filtering of CQMs to the following filters: 1. Taxpayer ID Number (TIN); 2. National Provider ID; 3. Provider type; 4. Practice site address; 5. Patient age; 6. Patient sex; 7. Patient race and ethnicity;	Again, this functionality is not yet available to most providers, so it is somewhat premature to know which filtering option generates more value. As a general rule, we believe additional filtering should emerge out of providers' needs, rather than regulation. One area that we urge more focus, is on enabling attribution of clinician performance. Attribution is a challenge and it will become more daunting moving forward. We do not believe National Provider ID or TIN is a sufficient identifier for individual physicians.

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	8. Patient problem list data. How useful are the "filtering" criteria to end users of systems for the purpose of safety and quality improvement? To quality improvement staff and organizations? Are there additional filters/data would be helpful to stratify CQM-filters data by?	

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